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| EXAMINER |
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THALER, MICHAEL H

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 12/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,414

Applicant(s)

SHANLEY, JOHN F.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-53,55 and 57-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-53,55 and 57-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 74 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 74, line and claim 84, line 2, there is no antecedent basis for "the ductile hinge". Further, it is not clear that the hinges are ductile since the hinges do not experience plastic deformation as indicated on page 9, lines 16-20 and page 16, lines 16-19 for example. Further, it is unclear what is meant by "transition regions" since no such regions are disclosed.

Claims 55 and 57-62 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Drasler et al. (6,451,051). Drasler et al., in figures 10A-10D, disclose beams 370, hinges (either portion 455 which is tapered in width 420 as shown in figure 10C or the combination of portion 455 and the transition region 410 which is also tapered in width). Alternatively, it would have been obvious that transition region 410 may be considered as part of a hinge since it is reduced in width as compared to the beams 370 and is directly attached to portion 455. The Drasler et al. hinge width, length and taper are inherently adjusted (i.e. chosen, when it is manufactured) such that they inherently

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achieve a particular value of maximum strain along the hinge (which is chosen by the designer of the device).

Claims 48-50, 52, 55, 57-59, 61, 63-65, 68, 74, 75, 78 and 84 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kranz (WO 98/18407). Kranz, in figures 1 and 2a-c, discloses beams (at the end of the lead line for reference numeral 4 in figure 1) and hinges (the narrowed regions in combination with the tapered transition portions at each end of the narrowed regions). Alternatively, it would have been obvious that each tapered, transition regions may be considered as part of a hinge since is it reduced in width as compared to the beams and is directly attached to the narrow portion. As to claims 48 and 63, the narrowed region and only the tapered portion closest to the apex of the V-shape of the Kranz device may be considered to be the claimed hinge. This Kranz hinge is tapered such that an end closest to the apex of the V-shape has a width which is greater than the width of the hinge at an opposite end. As to claim 55, The Kranz hinge width, length and taper are inherently adjusted (i.e. chosen, when it is manufactured) such that they inherently achieve a particular value of maximum strain along the hinge (which is chosen by the designer of the device). As

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to claims 68 and 78, the patentability of an apparatus does not depend upon it's method of manufacture.

Claims 51 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz (WO 98/18407) in view of Drasler et al. (6,451,051). As to claim 51, Kranz fails to disclose the hinges experiencing deformation below their elastic limit. However, Drasler et al. teaches that a stent should be constructed such that the hinges experiencing deformation below their elastic limit (col. 38, lines 37-42) apparently so that self-expansion of the stent can be achieved. It would have been obvious to insure that the Kranz hinges experience deformation below their elastic limit so that it too would have this advantage. As to claim 53, Kranz fails to disclose a structure adjacent the hinges which experiences two degrees of freedom of motion during expansion. However, Drasler et al. teach that a stent should include a structure 250 adjacent the hinge (col. 45, lines 1-3) which experiences two degrees of freedom of motion during expansion (1, the pivoting of barb 250 from the position shown in figure 11B to the position shown in figure 11D wherein the pivot point is near node 365 and 2, the straightening of the barb along its entire length from the curved configuration shown in figure 11B to a straight configuration as shown in figure 11D as it pivots as indicated

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above). This arrangement has the advantage of better securing the stent in place in the body due to the barb. It would have been obvious to include such a barb on the Kranz stent so that it too would have this advantage.

Claims 66, 67, 70, 71, 76, 77, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz (WO 98/18407). As to claims 66, 67, 76 and 77, Kranz fails to disclose teeth and a pawl. However, it is old and well known in this art to include disclose teeth and a pawl on a stent in order to insure that it remains expanded. It would have been obvious to include teeth and a pawl on the Kranz stent so that it too would have this advantage. As to claims 70, 71, 80 and 81, Kranz fails to disclose the amount of recoil claimed. However, it is old and well known in this art to construct stents with low recoil in order to insure that the blood vessel remains expanded. It would have been obvious to construct the Kranz stent with low recoil so that it too would have this advantage.

Claims 69, 72, 73, 79, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kranz (WO 98/18407) in view of Harish et al. (6,506,437). As to claims 69 and 79, Kranz fails to disclose apertures and a beneficial agent disposed therein. However, Harish et al. teach that a stent should include apertures and a beneficial agent disposed therein

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so that the beneficial agent can be reliably applied to the body. It would have been obvious to include apertures and a beneficial agent disposed therein in the Kranz stent so that it too would have this advantage. As to claims 72, 73, 82 and 83 note the biodegradable polymer disclosed by Harish et al. in col. 5, lines 21-22.

Applicant's arguments filed Dec. 4, 2003 have been fully considered but they are not persuasive. As to claim 48, the Kranz tapered transition regions are thinner than the relatively wide beams and would therefore inherently bend to some extent when sufficient force is applied to them. As to claim 55, the Drasler et al. and Kranz hinge width, length and taper are inherently adjusted (i.e. chosen, when it is manufactured) such that they inherently achieve a particular value of maximum strain along the hinge. This particular value of maximum strain along the hinge is chosen by the designer of the device when he or she chooses the hinge width, length and taper. Although this particular value of maximum strain may be different than the value in applicant's invention, this feature has not been claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is

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reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
12/17/03



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731